CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

DETECTING AND REPORTING SUSPICIOUS ORDERS AND RESPONDING TO THRESHOLD EVENTS

1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to provide guidance to Cardinal Health employees in the Quality and Regulatory Affairs (QRA) department on responding, detecting and reporting suspicious orders, and processing, documenting and making judgments about threshold events, including making decisions about adjusting thresholds, releasing orders, or cutting orders.

It is also the purpose of this SOP to comply with or exceed the standards for distributors set forth in the Controlled Substances Act, regulations promulgated pursuant to that Act, and extra-regulatory guidance to which Drug Enforcement Administration (DEA) holds distributors responsible.

2.0 SCOPE

This SOP applies when an order is triggered by the Cardinal Health Anti-Diversion Centralization (or equivalent) system for evaluation so as to meet the purpose of the SOP mentioned in §1.0 above.

3.0 REFERENCES / RELATED DOCUMENTS

[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008.docx"]{- HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008.docx" }	On-Site QRA and Surveillance Investigations
[HYPERLINK "http://www.fda.gov/regulatoryinformation/legislation/ucm148726.htm"]{- HYPERLINK "http://www.fda.gov/regulatoryinformation/legislation/ucm148726.htm" }	Controlled Substances Act
[HYPERLINK "http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/130	21 CFR 1301.74(b)

DEFENDANT EXHIBIT
CAH-WV-00104

1_74.htm"]{ HYPERLINK "http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_74.htm" }

4.0 RESPONSIBILITIES

The responsibilities of QRA includes

a. Evaluating threshold events
b. Identifying suspicious orders
c. Reporting suspicious orders to DEA
d. Performing a review of suspicious orders
e. Making decisions regarding threshold adjustments
f. Cutting suspicious orders when appropriate
g. Releasing portions of orders when appropriate

5.0 DEFINITIONS

Anti-Diversion Centralization (ADC) System — Case management system used to facilitate the evaluation and assessment of threshold events, which are orders for controlled substance products held by the Suspicious Order Monitoring (SOM) electronic monitoring program. The case management system also allows members of Quality and Regulatory Affairs to reference customer specific information, as well as make adjustments to threshold limits and restrict customers from purchasing controlled substances.

Threshold — The maximum quantity of a regulated drug permitted to be automatically shipped to a specific licensed customer.

Threshold Event — An order for a regulated drug which exceeds the threshold set for a specific licensed customer.

6.0 PROCEDURE

6.1 Initial Review

6.1.1 The following orders are held or cut pending review by QRA under this procedure

a. Orders of interest referred to by a Forward Distribution Center
b. Orders that exceed a threshold set for the customer for the drug family
c. Orders that exceed any other criteria established by QRA

6.1.2 In addition, under this SOP, QRA can review other orders that may come to the attention of QRA based on any other criteria.

6.1.3 Under this procedure, QRA must first review every held order under §6.1.1 to determine whether the order is suspicious as that term is used in [HYPERLINK "http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_74.htm"]{- HYPERLINK "http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_74.htm" }. Per the regulation, orders are deemed suspicious if they meet one (1) or more of three (3) criteria:

a. Order is of unusual size
b. Order is of unusual frequency
c. Order deviates substantially from a normal pattern for the customer

6.1.4 Orders that meet one or more of the criteria in §6.1.3 must be reported to the DEA as suspicious.

6.1.5 **Orders of unusual size** are significantly larger than the orders normally placed by the customer or by customers that have a size and type of business that is similar to the ordering customer's business.

6.1.5.1 Orders of unusual size can be as a result of:

a. Unintentional order entry errors (including duplicate order entries)
b. Intentional orders placed by the customer

QRA personnel must use available information and prior experience to determine if the order is an unintentional order entry error or intentional order placed by the customer.

6.1.5.2 Unintentional order entry errors (including duplicate order entries) must be cut and reported to the DEA as suspicious, with no changes to customer threshold.

6.1.5.3 QRA personnel must use available information and prior experience to determine if the order of unusual size is intentional. If QRA personnel determines the order to be intentional and of unusual size then the order is cut and reported to the DEA as suspicious.

6.1.6 **Orders of unusual frequency** are orders that occur significantly more frequently than the orders normally placed by the ordering customer or by customers that have a size and type of business that is similar to the ordering customer's business.

6.1.6.1 QRA personnel can use available information on order history and prior experience on other customers that have a size and type of business similar to the ordering customer to determine if the order is of unusual frequency.

6.1.6.2 If QRA personnel determines the order to be of unusual frequency then the order

is cut and reported to the DEA as suspicious.

6.1.7 **Orders that deviate substantially from the normal ordering pattern** are orders that reflect a significant deviation from the customer's normal orders or that deviate substantially from the ordering patterns of customers that have a size and type of business that is similar to the ordering customer's business.

6.1.7.1 Substantial deviations in ordering patterns include, but are not limited to,

a. Orders for an unusually high percentage of controlled substances compared to non-controlled substances.
b. Orders for an unusually high percentage of a particular strength of drug that is known or suspected of being widely diverted.
c. Orders that are cumulatively larger than expected for the customer even though individual orders may not be unusually large.
d. Other deviations based on QRA personnel's experience.

6.1.7.2 QRA personnel can use available information and prior experience on other customers that have a size and type of business similar to the ordering customer to determine if the order deviates substantially from the normal ordering pattern.

6.1.7.3 If the QRA personnel determines that the order deviates from normal ordering pattern then the order is cut and reported to the DEA as suspicious.

6.2 Review of Suspicious Orders

6.2.1 A held order that warrants an assessment is reviewed as described in written procedures to determine whether a threshold adjustment to the particular drug family is warranted.

6.2.1.1 When the QRA personnel determines that a threshold adjustment is warranted because the personnel has found that the drugs are unlikely to be diverted, the personnel must ensure that the reasons for adjusting the threshold and relevant information considered have been recorded prior to adjusting the threshold.

6.2.1.2 When the QRA personnel is unable to determine with information available that the order is not likely to be diverted, the current order and subsequent orders in the same drug family, above threshold, are cut, when appropriate, and reviewed on an individual basis to determine if a site visit is warranted.

6.2.2 **Selection of a suitable type of site visit** (refer to [HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008.docx"]{ HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Librar

~~y/CAD-C008.docx" }~~ for conducting site visits).

6.2.2.1 The site visit type is determined by QRA personnel following written procedures.

6.2.3 Decision based on findings of the site visit

6.2.3.1 If the decision is to suspend the customer, the current order and subsequent orders in the same drug family are cancelled and the threshold is set at one (1).

6.2.3.2 If the decision is to retain the customer, the QRA personnel must:

a. Continue to monitor the customer; and
b. Determine if the customer's threshold levels should be considered for adjustment and make adjustments if necessary following written procedures.

7.0 DOCUMENTATION REQUIREMENTS

7.1 Documentation Guide(s) and Practices

7.1.1 Not applicable.

7.2 Documentation Retention

7.2.1 Not applicable.

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Approvals					
Approvals on file in the Pharmaceutical Distribution Corporate Document Center Approvers: Todd Cameron				Owner: Danielle Holbrook PDCDC Coordinator: Jason Paul Snouffer	
Change History					
DCN	Effective Date	Change Type	Training Required	Document Applicability	Training Assignment(s)
3310	18 Jul 2013	Modify	Yes	Corporate	PDQRA - Analytics and SOM Compliance PDQRA - Pharmacy Assessment
Other (specify)					
N/A					
Change Description and Justification					
Review process for held orders has been enhanced and updated.; Document Approver was updated from Nicholas Rausch to Todd Cameron.					